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cd—Clinical dialogue  
efm—EFM today  
et—Equal time

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mu—Malpractice update  
nl—News from the literature  
oa—Original article

pr—Protocol  
ppc—Problem-patient  
conference  
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## Satric™ Tablets (metronidazole USP) 250 mg

**INDICATIONS AND USAGE:** Symptomatic Trichomoniasis: Satric is indicated for the treatment of symptomatic trichomoniasis in females and males when the presence of trichomonad has been confirmed by appropriate laboratory procedures (wet smears and/or cultures).

Asymptomatic Trichomoniasis: Satric is indicated in the treatment of asymptomatic females when the organism is associated with endocervicitis, cervicitis, or cervical erosion. Since there is evidence that presence of the trichomonad can interfere with accurate assessment of abnormal cytological smears, additional smears should be performed after eradication of the parasite.

Treatment of Asymptomatic Consorts: T. vaginalis infection is a venereal disease. Therefore, asymptomatic sexual partners of treated patients should be treated simultaneously if the organism has been found to be present in order to prevent reinfection of the partner. The decision as to whether to treat an asymptomatic male partner with a negative culture or one in whom no culture has been attempted is an individual one. In making this decision, it should be noted that there is evidence that women may become reinfected if the consort is not treated. Also, since there can be considerable difficulty in isolating the organism from the asymptomatic male carrier, negative smears and cultures cannot be relied upon in this regard. In any event, the consort should be treated with Satric in cases of reinfection.

Amebiasis: Satric is indicated in the treatment of acute intestinal amebiasis (amebic dysentery) and amebic liver abscess.

**CONTRAINDICATIONS:** Satric is contraindicated in patients with active organic disease of the central nervous system (See Adverse Reactions.)

Satric is contraindicated during the first trimester of pregnancy. (See Warnings.)

Satric is also contraindicated in patients with a prior history of hypersensitivity to metronidazole.

**WARNINGS:** Convulsive Seizures and Peripheral Neuropathy: Convulsive seizures and peripheral neuropathy, the latter characterized mainly by numbness or paresthesia of an extremity, have been reported in patients treated with metronidazole. The appearance of abnormal neurologic signs demands the prompt discontinuation of Satric therapy. Satric should be administered with caution to patients with central nervous system diseases.

Tumorigenicity Studies in Rodents: Metronidazole has shown evidence of tumorigenic activity in a number of studies involving chronic, oral administration in mice and rats.

Most prominent among the effects in the mouse was the promotion of pulmonary tumorigenesis. This has been observed in all five reported studies in that species, including one study in which the animals were dosed on an intermittent schedule (administration during every fourth week only). The published results of one of the mouse studies indicate an increase in the incidence of malignant lymphomas as well as pulmonary neoplasms associated with lifetime feeding of the drug. All these effects are statistically significant.

Two long-term toxicity studies in the rat have been completed. There was a statistically significant increase in the incidence of various neoplasms, particularly mammary tumors, among female rats administered metronidazole over that noted in the concurrent female control groups. Two lifetime tumorigenicity studies in hamsters have been performed and reported to be negative.

**PRECAUTIONS:** General: Patients with severe hepatic disease metabolize metronidazole slowly, with resultant accumulation of metronidazole and its metabolites in the plasma. Accordingly, for such patients, doses below those usually recommended should be administered cautiously.

Known or previously unrecognized candidiasis may present more prominent symptoms during therapy with Satric and requires treatment with a candidal agent.

Laboratory Tests: Satric (metronidazole) is a nitroimidazole and should be used with care in patients with evidence of, or history of blood dyscrasia. A mild leukopenia has been observed during its administration; however, no persistent hematologic abnormalities attributable to metronidazole have been observed in clinical studies. Total and differential leukocyte counts are recommended before and after therapy for trichomoniasis and amebiasis, especially if a second course of therapy is necessary.

Drug Interactions: Metronidazole has been reported to potentiate the anticoagulant effect of coumarin and warfarin resulting in a prolongation of prothrombin time. This possible drug interaction should be considered when Satric is prescribed for patients on this type of anticoagulant therapy.

Alcoholic beverages should not be consumed during Satric therapy because abdominal cramps, nausea, vomiting, headache, and flushing may occur.

Drug/Laboratory Test Interactions: Metronidazole may interfere with certain chemical analyses for serum glutamic oxalacetic transaminase, resulting in decreased values. Values of zero may be observed.

Carcinogenesis: (See Warnings.)

Pregnancy: Teratogenic Effects—Pregnancy Category B: Metronidazole crosses the placental barrier and enters the fetal circulation rapidly. Reproduction studies have been performed in rabbits and rats at doses up to five times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to metronidazole. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, and because metronidazole is a carcinogen in rodents, this drug should be used during pregnancy only if clearly needed. (See Contraindications.)

Use of Satric for trichomoniasis in the second and third trimesters should be restricted to those in whom local palliative therapy has been inadequate to control symptoms.

Nursing Mothers: Because of the potential for tumorigenicity shown for metronidazole in mouse and rat studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Metronidazole is secreted in breast milk in concentrations similar to those found in plasma.

Pediatric Use: Safety and effectiveness in children have not been established, except for the treatment of amebiasis.

**ADVERSE REACTIONS:** By far the most common adverse reactions have been referable to the gastrointestinal tract, particularly nausea, sometimes accompanied by headache, anorexia and occasionally vomiting, diarrhea, epigastric distress and abdominal cramping; constipation has also been reported. A metallic, sharp, unpleasant taste is not unusual. Furry tongue, glossitis and stomatitis have occurred; these may be associated with a sudden overgrowth of *Candida* which may occur during effective therapy. Proliferation of *Candida* also may occur in the vagina.

A moderate leukopenia may be observed occasionally. If this occurs, the total leukocyte count may be expected to return to normal after the course of medication is completed.

If patients receiving Satric (metronidazole) drink alcoholic beverages, they may experience abdominal distress, nausea, vomiting, flushing, or headache. A modification of the taste of alcoholic beverages has also been reported.

Dizziness, vertigo, incoordination, ataxia, convulsive seizures, and peripheral neuropathy have been reported. Numbness or paresthesia of an extremity and fleeting joint pains sometimes resembling "serum sickness" have been experienced, as have confusion, irritability, depression, weakness, insomnia, and a mild erythematous eruption.

Urticaria, flushing, nasal congestion, dryness of the mouth (or vagina or vulva), pruritus, dysuria, cystitis, and a sense of pelvic pressure have been reported. Very rarely dyspareunia, fever, polyuria, incontinence, decrease of libido, proctitis, and pyuria have occurred in patients receiving the drug.

Instances of darkened urine have been reported and this manifestation has been the subject of a special investigation. Although the pigment which is probably responsible for this phenomenon has not been positively identified, it is almost certainly a metabolite of metronidazole. It seems certain that it is of no clinical significance and may be encountered only when Satric (metronidazole) is administered in higher-than-recommended doses.

Flattening of the T-wave may be seen in electrocardiographic tracings.

**DOSEAGE AND ADMINISTRATION:** Trichomoniasis: In The Female: The recommended dosage is one 250 mg tablet orally 3 times daily for 7 days.

**CAUTION:** Federal law prohibits dispensing without prescription.



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